

PCT

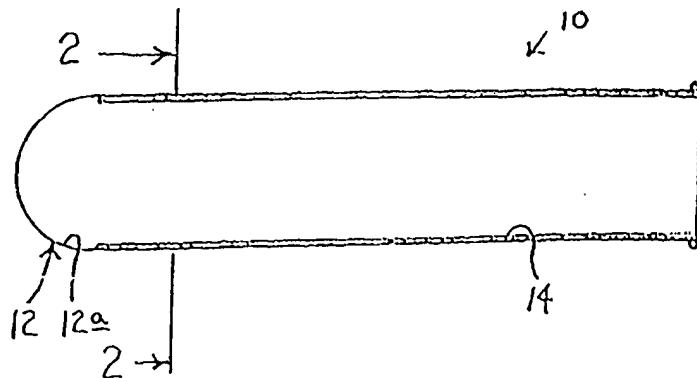
WORLD INTELLECTUAL PROPERTY ORGANIZATION
International Bureau



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 6 : A61F 6/02	A1.	(11) International Publication Number: WO 98/27899 (43) International Publication Date: 2 July 1998 (02.07.98)
(21) International Application Number: PCT/US97/22449 (22) International Filing Date: 10 December 1997 (10.12.97) (30) Priority Data: 08/771,229 20 December 1996 (20.12.96) US (71)(72) Applicant and Inventor: BENDIS, Ina, K. [US/US]; Suite 114, 851 Fremont Avenue, Los Altos, CA 94024 (US). (74) Agents: KOLISCH, J., Pierre et al.; Kolisch, Hartwell, Dickinson, McCormack & Heuser, Suite 200, 520 S.W. Yamhill Street, Portland, OR 97204 (US).	(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG). Published <i>With international search report.</i>	

(54) Title: PROPHYLACTIC SYSTEM WITH VASODILATOR-CONTAINING FILM



(57) Abstract

A prophylactic system (10) includes a vasodilator containing film (14) for use on a patient's or user's body. The prophylactic system (10) includes a first expanse of expandable support material (12) constructed for attachment to a desired section of such a patient's body. A vasodilator containing film (14) is formed over substantially the entire inner surface (12a) of the support material (12). There is also a condom-like system (110) including a sheath (112), and vasodilator containing material (114). A combination method of promoting vasodilation of a penis to facilitate penile erection, and preventing conception.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

AL	Albania	ES	Spain	LS	Lesotho	SI	Slovenia
AM	Armenia	FI	Finland	LT	Lithuania	SK	Slovakia
AT	Austria	FR	France	LU	Luxembourg	SN	Senegal
AU	Australia	GA	Gabon	LV	Latvia	SZ	Swaziland
AZ	Azerbaijan	GB	United Kingdom	MC	Monaco	TD	Chad
BA	Bosnia and Herzegovina	GE	Georgia	MD	Republic of Moldova	TG	Togo
BB	Barbados	GH	Ghana	MG	Madagascar	TJ	Tajikistan
BE	Belgium	GN	Guinea	MK	The former Yugoslav Republic of Macedonia	TM	Turkmenistan
BF	Burkina Faso	GR	Greece	ML	Mali	TR	Turkey
BG	Bulgaria	HU	Hungary	MN	Mongolia	TT	Trinidad and Tobago
BJ	Benin	IE	Ireland	MR	Mauritania	UA	Ukraine
BR	Brazil	IL	Israel	MW	Malawi	UG	Uganda
BY	Belarus	IS	Iceland	MX	Mexico	US	United States of America
CA	Canada	IT	Italy	NE	Niger	UZ	Uzbekistan
CF	Central African Republic	JP	Japan	NL	Netherlands	VN	Viet Nam
CG	Congo	KE	Kenya	NO	Norway	YU	Yugoslavia
CH	Switzerland	KG	Kyrgyzstan	NZ	New Zealand	ZW	Zimbabwe
CI	Côte d'Ivoire	KP	Democratic People's Republic of Korea	PL	Poland		
CM	Cameroon	KR	Republic of Korea	PT	Portugal		
CN	China	KZ	Kazakhstan	RO	Romania		
CU	Cuba	LC	Saint Lucia	RU	Russian Federation		
CZ	Czech Republic	LI	Liechtenstein	SD	Sudan		
DE	Germany	LK	Sri Lanka	SE	Sweden		
DK	Denmark	LR	Liberia	SG	Singapore		

PROPHYLACTIC SYSTEM
WITH VASODILATOR-CONTAINING FILM

Background and Summary of the Invention

The present invention relates generally to medical products in the form of 5 chemical agents that increase blood flow. More particularly, the invention concerns a novel prophylactic system with a vasodilator-containing film, which system is useful to treat impotency and other diseases or physical conditions where treatment requirements include increased blood flow.

It is known that impotency occurs in a substantial portion of the male 10 population. Impotency takes two forms, physiological and psychological. A male who has psychological impotency is physically capable of having an erection, but unable to achieve the same for psychological reasons.

There have been a number of conventional proposals for diagnosing the particular form of impotency and treating the psychological form. In connection with such 15 treatments, U.S. Patent No. 4,829,991 to Boeck describes a condom with an interior surface coated with a transdermal nitroglycerin (NTG) coating, a known vasoactive dilator. The idea is for a male to stimulate an erection in his penis by placing the NTG-coated condom over it.

There are several drawbacks to the condom proposed by Boeck. First, that 20 condom will not stimulate an erection in a number of males with psychological impotency because the construction of the condom requires that the male user's penis be sufficiently erect to use it. In other words, the Boeck proposal surprisingly requires that the condom user has the very capability the user lacks, and for which the user is seeking treatment. A substantial percentage of males with psychological impotency cannot achieve the requisite

degree of penile erection to use the Boeck condom.

A further, essential drawback with Boeck is that it proposes coating the interior surface of the condom with conventional transdermal NTG adhesive coating or patch. There is no clinical evidence that such convention transdermal NTG adhesive coatings are effective to release transdermally an effective amount of NTG into the user's blood.

Other conventional proposals involve topically applying NTG-containing cream directly to the penis before intercourse. The essential drawback with such proposals is that the NTG present on the user's penis is transmitted to the user's sexual partner, and that NTG can have deleterious health effects on the user's sexual partner.

With respect to other diseases or physical conditions where treatment requirements include increased blood flow, conventional proposals have been lacking in showing devices or methods to increase blood flow noninvasively and effectively. One example of such diseases and conditions is known as Raynaud's syndrome which involves vasoconstriction of blood vessels in the fingers and toes. The result is to cause affected appendages to become cold, dry, painful, and unattractive in appearance. Another example of such diseases and conditions is frostbite.

Until now, there has been no effective proposal to promote blood flow to treat psychological impotency and such other diseases and conditions.

Accordingly, it is a principal object of the present invention to provide a device and treatment method that overcomes the drawbacks of prior-art proposals.

Yet another object is to provide such device and method that is usable by male users who lack the ability of achieving enough of a penile erection to use a condom.

Another object is to provide such device and method that is usable to treat Raynaud's syndrome.

Yet another object is to provide such device and method that is usable to treat frostbite.

5 Another important object of the invention is to provide such device and method that promotes penile erection in males but also provides other health advantages.

Still another object is to provide such device and method that encourages the use of condoms among males who have psychological impotency as a way of diminishing the occurrence of unwanted pregnancies and/or sexually transmitted diseases
10 in the males' sexual partners.

Another object is to provide such device and method that tends to prevent heart attacks during sexual intercourse in males who have both psychological impotency and atherosclerotic coronary vascular disease.

It is also an object of the invention to provide such device and method that
15 can be cost-effectively manufactured and practiced, respectively.

In brief summary, one aspect of the invention includes a prophylactic system with a vasodilator-containing film for use on a patient's, or user's, body. The prophylactic system includes a first expanse of expandable support material constructed for attachment to a desired section of such a patient's body. A vasodilator-containing film
20 is formed over substantially the entire inner surface of the support material. The first expanse of may be formed as one of the group consisting of a patch, strip, tape, sheath, or condom. In a first preferred embodiment, the first expanse is formed as a sheath and is constructed for enclosing a protuberant section of the patient's body such as an appendage, penis, finger, toe, or ear.

These and other objects and advantages of the invention will be more clearly understood from a consideration of the following description of the preferred embodiments.

Brief Description of the Drawings

5 Fig. 1 is a side view of the preferred embodiment of the prophylactic system of the invention.

Fig. 2 is a fragmentary cross-sectional view through line 2-2 of Fig. 1.

Fig. 3 shows alternate embodiments of a first expanse element of the invention.

10 Fig. 4 is a third embodiment of the invention.

Fig. 5 is a fourth embodiment of the invention.

Fig. 6 is a fragmentary view of a fifth embodiment of the invention.

Detailed Description of the Preferred Embodiment and
the Preferred Manner of Practicing the Invention

15 The preferred embodiment of the prophylactic system of the invention is shown in Fig. 1 at 10 and includes a first expanse 12 of expandable support material constructed for attachment to a desired section of a patient's body, with the support material including an inner surface 12a. An example of support material is a conventional condom. System 10 also includes a vasodilator-containing film 14 formed over 20 substantially the entire inner surface of the support material. The rheology of the vasodilator film is to have an optimal viscosity and thixotropy to allow the film to remain on interior surface 12a even when the condom is rolled in the usual way for anti-contamination or sterile packaging. The film must not however be so viscous as to prevent effective transmission of the vasodilator material to the penis, thereby to induce blood flow

to the veins of the penis. The film may also be thought of as a coating or as material. The vasodilator may be any known substance that tends to dilate veins/arteries. Fig. 2 shows a fragmentary cross section of system 10 when it is placed over a desired section of a patient's body such as a protuberance like penis 16.

5 The vasodilator-containing film is formed as a moist composite that includes a vasodilator, such as a nitrate-containing chemical, dispersed in an adhesive carrier. The adhesive carrier is operative to adhere the vasodilator-containing film to the inner surface of the support material, and the vasodilator is in a preselected concentration that effects release into the epidermoid layer of the user's skin when the prophylactic 10 system is placed over the desired section of the user's skin.

A second preferred embodiment of the prophylactic system further includes a second expanse of expandable support material, with the first expanse being formed as a patch 18, a strip or tape 20 (see Fig. 3), and the second expanse being formed as a sheath or condom (such as expanse 12 in Fig. 1).

15 Referring to Fig. 4, a third preferred embodiment of the prophylactic system is a condom-like system 110 that includes a sheath 112, and a layer of vasodilator-containing material 114. The sheath is formed as a composite and includes inner layer 114 formed of the vasodilator-containing material. For this embodiment the sheath is preferably constructed for use as a condom to be placed over a penis of a male user, and 20 the sheath includes a first reservoir 122 that holds a preselected amount 124 of the vasodilator-containing material. The sheath also includes a breakable internal membrane 126 defining an inner boundary of the reservoir, with breaking of the internal membrane allowing release of the vasodilator-containing material from the reservoir to allow contact with the penis as a way of promoting a penile erection. The sheath also preferably

includes a second reservoir for holding penile ejaculate and that reservoir can take the form of the usual reservoir in conventional condoms. Referring to Fig. 5, the first and second reservoirs may be formed as one reservoir 322 with two compartments 322 a, 322b.

5 A fourth preferred embodiment includes the sheath of the third preferred embodiment, and certain other elements including an anti-contamination protector wearable on the hand of the user, and an applicator for applying the vasodilator-containing material to such protuberant section of such user's body.

10 A fifth preferred embodiment includes the sheath of the third preferred embodiment, and certain other elements including an anti-contamination dispenser for holding a preselected amount of the vasodilator-containing material and for dispensing the vasodilator-containing material on such protuberant section of such user's body.

15 A sixth preferred embodiment (see Fig. 4) includes the sheath of the third preferred embodiment constructed as a penile cap 210 for removably fitting over the head (undepicted) of a penis of a male user. The penile cap includes a penile-head covering 212 and a fastener (such as an elastic band 213) for fastening it to the head of the user's penis.

Another aspect of the invention is a combination method of promoting vasodilation of a penis to facilitate penile erection, and preventing conception. The method includes the steps of applying a vasodilator-containing material topically to such 20 penis to produce a penile erection, and fitting a prophylactic over such penis after such penile erection is produced. For the fitting step, the preferred prophylactic is the prophylactic system described in connection with the system of the invention.

The above devices and methods of the invention meet the above objects by providing devices and methods for the male user to (1) promote desired occurrence of a

penile erection, (2) prevent conception and transmission of sexually transmitted diseases such as AIDS, and (3) exhibit other positive health effects such as tending to prevent heart attacks during sexual intercourse in males who have both psychological impotency and atherosclerotic coronary vascular disease.

5 Accordingly, while a preferred embodiment of the invention has been described herein, it is appreciated that modifications are possible that are within the scope of the invention.

I CLAIM:

1. A prophylactic system with a vasodilator-containing film for use on a patient's body, comprising:

a first expanse of expandable support material constructed for attachment to a desired section of such a patient's body, with the support material including an inner surface; and

a vasodilator-containing film formed over substantially the entire inner surface of the support material.

2. The prophylactic system of claim 1, wherein the first expanse of expandable support material is formed as one of the group consisting of a patch, strip, tape, sheath, or condom.

3. The prophylactic system of claim 2, wherein the first expanse is formed as a sheath and is constructed for enclosing a protuberant section of the patient's body.

4. The prophylactic system of claim 3, wherein the protuberant section is chosen from the group consisting of an appendage, penis, finger, toe, or ear.

5. The prophylactic system of claim 1, wherein such patient has a skin-covered body, and which skin includes an epidermoid layer, and wherein the vasodilator-containing film is formed as a moist composite that includes a vasodilator dispersed in an adhesive carrier, with the adhesive carrier operative to adhere the vasodilator-containing film to the inner surface of the support material, and the vasodilator being present in a preselected concentration that effects release into the epidermoid layer of the desired section when the prophylactic system is placed over the desired section.

6. The prophylactic system of claim 1 or 5 further including a second expanse of expandable support material, with the first expanse being formed as one of the group consisting of a patch, strip, or tape, and the second expanse being formed as one of the group consisting of a sheath or condom.

7. A condom-like system for use on a protuberant section of a user's body, comprising:

a sheath; and
a vasodilator-containing material.

8. The system of claim 7, wherein the sheath is formed as a composite and includes an inner layer formed of the vasodilator-containing material.

9. The system of claim 8, wherein such user has a skin-covered body, and which skin includes an epidermoid layer, and wherein the vasodilator-containing material is formed in a moist composition that includes a vasodilator dispersed in an adhesive carrier, with the adhesive carrier operative to adhere the vasodilator-containing material to the remainder of the sheath, and the vasodilator being present in a preselected concentration that effects release into the epidermoid layer of the desired section when the system is placed over the desired section.

10. The system of claim 9, wherein the sheath is constructed for use as a condom to be placed over a penis of a male user, and the sheath includes a first reservoir that holds a preselected amount of the vasodilator-containing material.

11. The system of claim 10, wherein the sheath includes a breakable internal membrane defining an inner boundary of the reservoir, with breaking of the internal membrane allowing release of the vasodilator-containing material from the reservoir to allow contact with the penis as a way of promoting a penile erection.

12. The system of claim 11, wherein the sheath includes a second reservoir for holding penile ejaculate.

13. The system of claim 12, wherein the first and second reservoirs are formed as one reservoir with two compartments.

14. The system of claim 7, further including an anti-contamination protector wearable on the hand of the user, and an applicator for applying the vasodilator-containing material to such protuberant section of such user's body.

15. The system of claim 7, further including an anti-contamination dispenser for holding a preselected amount of the vasodilator-containing material and for dispensing the vasodilator-containing material on such protuberant section of such user's body.

16. The system of claim 9, wherein the sheath is constructed as a penile cap for removably fitting over the head of a penis of a male user.

17. The system of claim 16, wherein the penile cap includes a penile-head covering and a fastener for fastening the penile cap to the head of a penis.

18. The system of claim 17, wherein the penile-head covering is formed as a composite and includes an inner layer formed of the vasodilator-containing material.

19. The system of claim 18, wherein such user has a skin-covered body, and which skin includes an epidermoid layer, and wherein the vasodilator-containing material is formed in a moist composition that includes a vasodilator dispersed in an adhesive carrier, with the adhesive carrier operative to adhere the vasodilator-containing material to the remainder of the penile-head covering, and the vasodilator being present in a preselected concentration that effects release into the epidermoid layer of the desired section when the system is placed over the desired section.

20. The system of claim 19, wherein the penile-head covering includes a first reservoir that holds a preselected amount of the vasodilator-containing material.

21. The system of claim 20, wherein the penile-head covering includes a breakable internal membrane defining an inner boundary of the reservoir, with breaking of the internal membrane allowing release of the vasodilator-containing material from the reservoir to allow contact with the penis as a way of promoting a penile erection.

22. The system of claim 21, wherein the penile-head covering includes a second reservoir for holding penile ejaculate.

23. The system of claim 22, wherein the first and second reservoirs are formed as one reservoir with two compartments.

24. The system of claim 17, further including an anti-contamination protector wearable on the hand of the user, and an applicator for applying the vasodilator-containing material to the penis of the user.

25. The system of claim 17, further including an anti-contamination dispenser for holding a preselected amount of the vasodilator-containing material and for dispensing the vasodilator-containing material on the penis of the user.

26. A condom for use on a penis of a male user, comprising:

a vasodilator cream;

a composite sheath including an inner layer formed of the vasodilator cream; wherein such user has a skin-covered body, and which skin includes an epidermoid layer, and wherein the vasodilator cream is formed in a moist composition that includes a vasodilator dispersed in an adhesive carrier, with the adhesive carrier operative to adhere the vasodilator cream to the remainder of the sheath, and the vasodilator being present in a preselected concentration that effects release into the epidermoid layer of the desired section when the system is placed over the desired section; and

wherein the sheath includes a first reservoir that holds a preselected amount of the vasodilator cream, and a breakable internal membrane defining an inner boundary of the reservoir, with breaking of the internal membrane allowing release of the vasodilator-containing material from the reservoir to allow contact with the penis as a way of promoting a penile erection.

27. The system of claim 26, wherein the sheath includes a second reservoir for holding penile ejaculate.

28. The system of claim 27, wherein the first and second reservoirs are formed as one reservoir with two compartments.

29. A combination method of promoting vasodilation of a penis to facilitate penile erection, and preventing conception, comprising:

applying a vasodilator-containing material topically to such penis to produce a penile erection; and

fitting a prophylactic over such penis after such penile erection is produced.

30. The method of claim 29 wherein the applying step includes using a pharmaceutically-effective amount of vasodilator-containing material that is prescribed by a health professional.

31. The method of claim 30 wherein the applying step includes using a cosmetically-effective amount of vasodilator-containing material.

FIG. 1

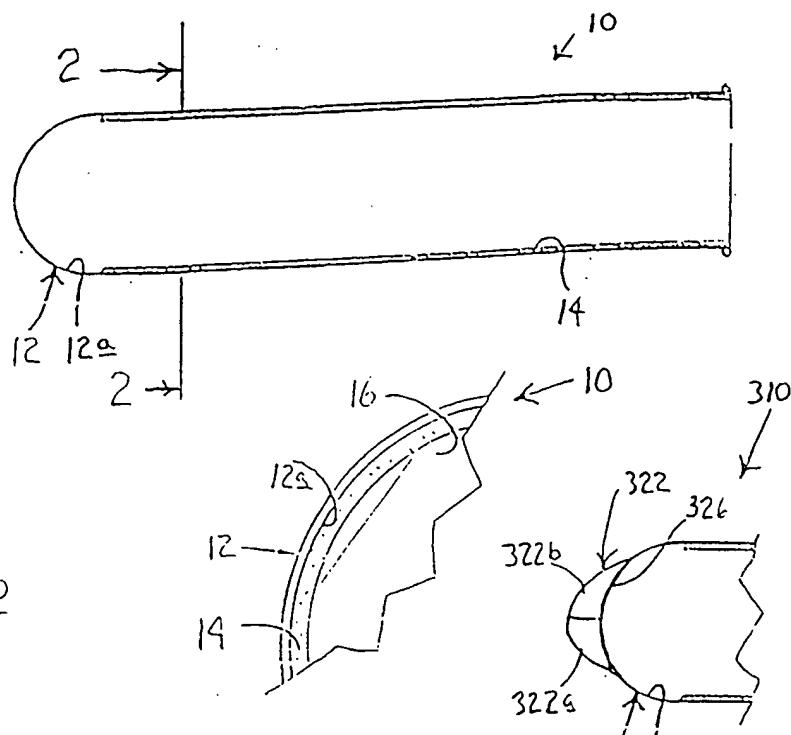


FIG. 2

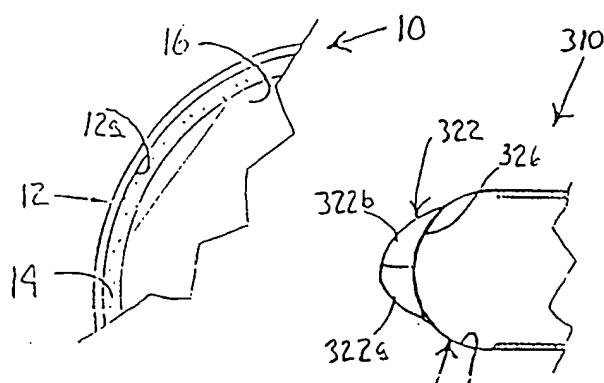


FIG. 3

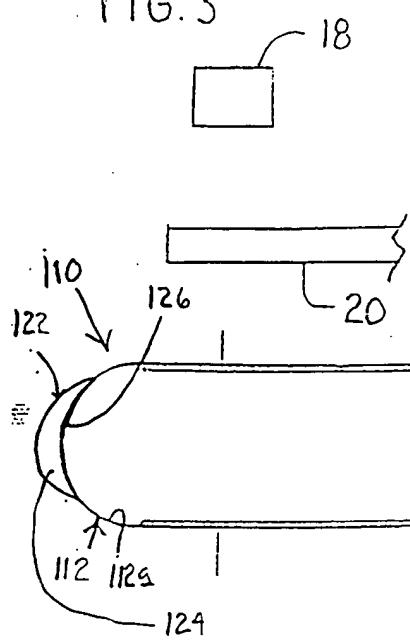


FIG. 6

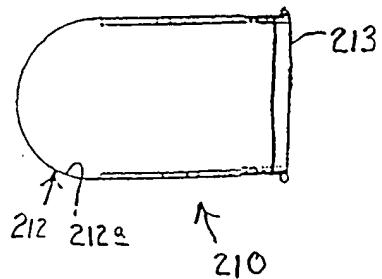
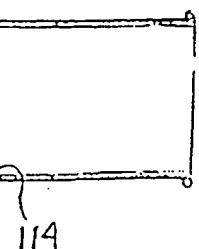


FIG. 5

FIG. 4



INTERNATIONAL SEARCH REPORT

International application No.
PCT/US97/22449

A. CLASSIFICATION OF SUBJECT MATTER

IPC(6) : A61F 6/02

US CL : 128/842

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 128/842-844; 600/038-041

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 4,829,991 A (BOECK) 16 May 1989, entire document.	1-9
---		-----
Y		10-31
Y	US 4,332,243 A (GUTNICK) 01 June 1982, entire document.	1-13,15-28
Y	US 5,421,350 A (FRIEDMAN) 06 June 1995, entire document.	12, 13, 16-25, 27, 28

Further documents are listed in the continuation of Box C.

See patent family annex.

- * Special categories of cited documents:
- "I" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "A" document defining the general state of the art which is not considered to be of particular relevance
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "E" earlier document published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed
- "A" document member of the same patent family

Date of the actual completion of the international search

27 FEBRUARY 1998

Date of mailing of the international search report

20 MAR 1998

Name and mailing address of the ISA/US
Commissioner of Patents and Trademarks
Box PCT
Washington, D.C. 20231

Facsimile No. (703) 305-3230

Authorized officer

JOHN LACYK

Telephone No. (703) 308-2995